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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,308	07/29/2003	Zhong Zhang	TP1P018	6429

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/629,308		ZHANG ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Shirley V. Gembeh		1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-14 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 15-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6,8-14 and 17-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-6, 8-14 and 17-24 are pending.

Claims 7 and 15-16 are cancelled.

The amendment to the claims filed December 23, 2005 has been received and entered.

### ***Response to Arguments***

Applicant has amended the claims in such a way that it will be an undue burden to the examiner, therefore election of species is required. Additionally, the various recited Markush elements have varying subclasses in class 514. Thus there is separate classification. In addition, each has attained a separate status in the art as evident by their separate classification. Furthermore, a search of any one Markush element would not have resulted in a complete search of all US patent foreign patent and non-patent technical literature. Thus, per MPEP 803, then is a serious burden.

The practice, re: Markush claims encompassing multiple independent and patentably distinct inventions is set forth in M.P.E.P. 803. The following requirement to make a provisional election of a single independent and patentably distinct invention is made pursuant to said practice.

Claim 2 is drawn in Markush format encompass multiple and patentably distinct inventions. The claim is drawn to different types of excipient used. It is pointed out that the claim is directed to a series of different excipient encompass in terms of the final species/compound/composition: for example Poloxamer (classified in class 514/675+), benzalkonium chloride (classified in class 514/715, 716+), Polyoxyethylene 40 stearate (classified in class 528/295).

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Claim 3 is drawn in Markush format encompass multiple and patentably distinct inventions. The claim is drawn to different types of excipient used. It is pointed out that the claim is directed to a combination of different excipient encompass in terms of the final species/compound/composition:

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- a) Benzalkonium chloride, Cremophor EL;
- b) Benzalkonium chloride, Poloxamer 237;
- c) Benzalkonium chloride, Benzethonium chloride, Poloxamer 237;
- d) Benzalkonium chloride, Cremophor EL, Polysorbate 80;
- e) Benzalkonium chloride, Cremophor EL, Propylene Glycol;
- ~~f) Benzalkonium chloride, Cremophor EL;~~
- g) Benzalkonium chloride, PEG 400, Poloxamer 237;
- h) Benzalkonium chloride, Poloxamer 188, Poloxamer 338;
- i) Benzalkonium chloride, Poloxamer 188;
- j) Benzalkonium chloride, Poloxamer 237, Polyoxyethylene 40 Stearate;

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- k) Benzalkonium chloride, Poloxamer 237, Polysorbate 80;
- l) Benzalkonium chloride, Poloxamer 237, Propylene Glycol;
- m) Benzalkonium chloride, Poloxamer 237, vitamine E TPGS;
- n) Benzalkonium chloride, Poloxamer 237, Saccharin sodium;
- o) Benzalkonium chloride, Poloxamer 338;
- ~~p) Benzalkonium chloride, Poloxamer 338;~~
- q) Benzalkonium chloride, Poloxamer 407;
- r) Benzalkonium chloride, Poloxamer 407, Polyoxyethylene 40 Stearate;
- s) Benzalkonium chloride, Poloxamer 407, Polysorbate 80;
- t) Benzalkonium chloride, Poloxamer 407, vitamine E TPGS;
- u) Benzethonium chloride, Cremophor EL;
- v) Benzethonium chloride, Cremophor EL, PEG 400;
- w) Benzethonium chloride, Cremophor EL, Poloxamer 237;
- x) Benzethonium chloride, Cremophor EL, Poloxamer 338;
- y) Benzethonium chloride, Cremophor EL, Poloxamer 407;
- z) Benzethonium chloride, Cremophor EL, Polysorbate 80;
- aa) Benzethonium chloride, Cremophor EL, Propylene Glycol;
- bb) Benzethonium chloride, Cremophor EL, vitamine E TPGS;
- ~~cc) Benzethonium chloride, Cremophor EL;~~
- dd) Benzethonium chloride, PEG 400, Poloxamer 188;
- ee) Benzethonium chloride, PEG 400, Poloxamer 237;
- ff) Benzethonium chloride, PEG 400, Poloxamer 338;
- gg) Benzethonium chloride, PEG 400, Poloxamer 407;

etc. It is considered

that a Markush type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and

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diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claim anticipated or obvious under 35 U.S.C. 102 nor 35 U.S.C. 103 respectively with regard to any one other of the species. Further these species are considered to be independent since they are unconnected in operation, one does not require the others for ultimate use and the specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered patentably distinct from the others on the basis of its properties. Thus, the exemplified species are, along with all other listed species capable of supporting separate patents under 35 U.S.C. 121.

Propofol is classified in class 514/579, 595,

Benzalkonium chloride is classified in class 514/715, 716, 717

Poloxamer is classified in class 514/675+

Polyoxyethelene 40 sterate is classified in class 528/295,

Saccharin sodium is classified in class 514/372,

Vitamine E is classified in class 514/456, as shown these are few examples of divergency in the search and because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent class subject matter, election for examination purposes as indicated is proper. Notwithstanding that the classification of some of the claimed compounds are patentable distinct and are fully capable of supporting separate status. In each of the above, the search for the compounds for example vitamine E is not readily expected to have resulted in a complete search of the relevant patent and non

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patent literature to include benzalkonium chloride or poloxamer for any one other invention.

Accordingly, applicants are required to make a provisional election of a single independent and /or patentably distinct Invention stated *supra* prior to an examination of said species on the merits. Applicant is required to described a single species within the genus group. This election will be given effect in the event the Markush type claims are not found allowable, at which time the examination of the claims presented will be limited to the Markush type claims and claims directed solely to the elected species. The claims directed solely to the nonelected species will be held withdrawn from further consideration. It should be noted that an election of species has been held to be tantamount to a requirement for restriction (see *In re Herrick*, 1958 CD 1, and *In re Joyce* 1958 CD2).

Applicant's response must include a provisional election of one of the independent and patentably distinct inventions identified above even though the requirement is traversed (37 C.F.R. 1.142 and 1.143). Applicant is advised that any traverse must be supported by argument in order to perfect the right to petition in the event that the provisional requirement is given effect in the event noted above.

A shortened statutory period for response to this action is set to expire 30 days from the date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
2/17/06

  
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